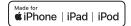
mplifon



ampli-energy

R (5,4,3,2) P R PH, R trial P User Guide







This user guide is valid for:

Wireless hearing aids	(t
	0459
ampli-energy R 5 5P R PH	2020
ampli-energy R 4 5P R PH	2020
ampli-energy R 3 5P R PH	2020
ampli-energy R 2 5P R PH	2020
ampli-energy R trial 5P	2020

Non wireless charging accessories

2019
2019
2021
2021



Your hearing aid details

- (i) If no box is checked and you do not know the model of your hearing aid or charging accessories, please ask your hearing care professional.
- (i) The hearing aids described in this user guide contain a built-in and non-removable rechargeable lithium-ion battery.
- (i) The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.
- (i) Please also read safety information regarding handling rechargeable hearing aids (chapter 23).

Hearing aid models

ampli-energy R (5/4/3/2) P R PH ampli-energy R trial P

Charger

ampli-charge B-R 1* ampli-charge R small 1* ampli-charge R 1 compact*

Power Pack

* Incl. power supply and USB cable (< 3 m)

Earpieces

□ Dome ☐ SlimTip

□ cShell

Please read the User Guide carefully to make sure that you understand and get the best out of hearing aids. For more information regarding features, benefits, setup, use and maintenance or repairs of your hearing aid and accessories – contact your hearing care professional. Additional information can be found in the Data Sheet of your product.

Contents

	Your hearing aid and charger			Further information	
1.	Quick guide	8	16.	Operating, transport and storage conditions	4
2.	Parts of the hearing aid & charger	11	17.	Care and maintenance	4
	Using the charger		18.	Exchanging the earwax protection	5
3.	Preparing the charger	17	19.	Service and warranty	6
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1. Quick guide

Charging your hearing aids

(j) Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.

After placing your hearing aid in the charger, the indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.





Left & right hearing aid markings





Blue marking for **left hearing aid.**

Red marking for right hearing aid.

Multi-function button with indicator light

The button has several functions. It functions as an on/off switch, a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual instructions.

Phone calls: If paired with a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call.



On/Off: Firmly press the lower part of the button for 3 seconds until the indicator light blinks.

On: indicator light is solid green
Off: indicator light is solid red

Enter flight mode: When device is off, press the lower part of the button for 7 seconds until the solid orange light appears. Then release the button.

Tap Control (only available for models 5 and 4)

If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control, please refer to chapter 10.

This is also indicated in your individual instructions. To use tap control tap the top of your ear twice.

2. Parts of the hearing aid & charger

The following pictures show the hearing aid model and charger accessories described in this user guide. You can identify your personal models by:

- checking "Your hearing aid & charger details" on page 3.
- comparing your hearing aid and charger with the following models.

Possible earpieces





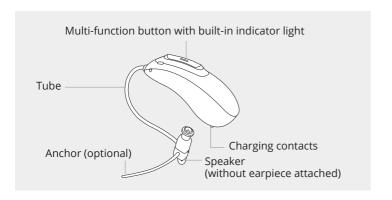


SlimTip

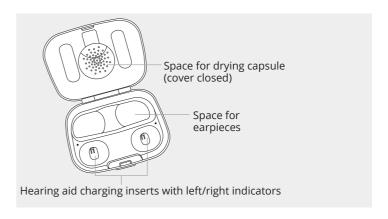


cShell

ampli-energy R P R PH ampli-energy R trial P

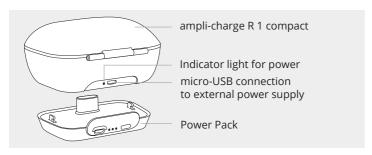


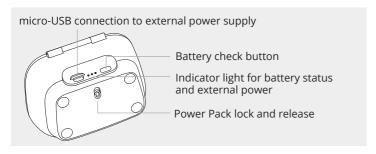
ampli-charge R 1 compact



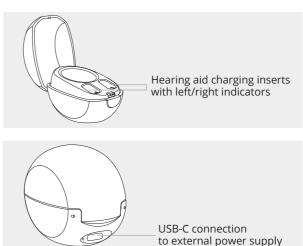


ampli-charge R 1 compact with optional Power Pack





ampli-charge



Indicator light for power

External power supply



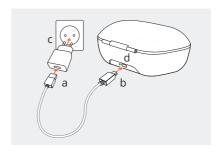


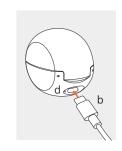
USB cable (< 3 m)

Power supply

3. Preparing the charger

Connecting the power supply





- a) Plug the larger end of the charging cable into the power supply.
- b) Plug the smaller end into the USB port on the charger.
- c) Plug the power supply into a power outlet.
- d) The indicator light is green when the charger is connected to the power supply.

Power supply specification

Power supply output voltage	5 VDC +/-10%, current 500 mA
Power supply input voltage	100-240 VAC, 50/60Hz, current 250 mA

Charger specification

Charger input voltage	5 VDC +/-10%, current 500 mA
USB cable specifications	5 V min. 1 A, USB-A to USB-C, maximum length 3 m

4. Charging the hearing aids

- (i) Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).
- i The hearing aid contains a built-in and non-removable rechargeable lithium-ion battery.
- i Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.
- i The hearing aid must be dry before charging, see chapter 17.
- (i) Please ensure to charge and use the hearing aid within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

Using the ampli-charge

Please refer to chapter 3 for how to set up the charger.



Insert the hearing aid into the charging inserts.

Make sure the left and right hearing aid markings match the left (blue), right (red) indicators next to the charging inserts. The hearing aids will automatically be switched off when inserted into the charger.







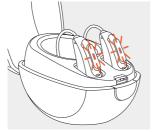
The indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will remain on, i.e. solid green light.

The charging process will automatically stop when the batteries are fully charged, so the hearing aids can be safely left in the charger. It can take up to 3 hours to charge the hearing aids. The charger covers can be closed while charging.

Charging times

Indicator light	Charging state	Charging times
0 0 0	0 – 10%	
• • •	11 – 80%	30 min (30%) 60 min (50%) 90 min (80%)
0 0 0	81 – 99%	
	100%	3 h



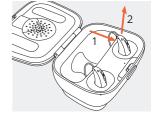




Remove the hearing aids from the charging inserts by

- 1. pulling the hearing aids gently toward yourself and
- 2. lifting them out of the charger.

The hearing aid switches on automatically when removed from the charger. The indicator light starts blinking. The solid green light indicates the hearing aid is ready.





If you unplug the charger while the hearing aid is charging inside, please

make sure to turn off the hearing aid to prevent discharge.

- (j) Do not hold the tubes to remove the hearing aids from the charger as this can damage the tubes.
- Turn off your hearing aid before inserting it in the disconnected charger to store it.

Using the optional Power Pack

Note: The Power Pack is only compatible with the ampli-charge R 1 compact



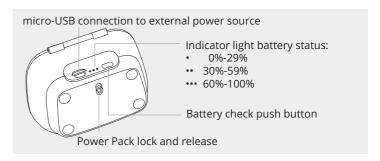
Attach the Power Pack to the bottom of the Charger Case and lock it.





Plug in the micro-USB and connect to an external power supply. The Power Pack and hearing aids will be charged at the same time. While connected to an external power supply, the Power Pack indicator light will show the current battery charge status of the Power Pack.

- (j) Before using Power Pack for the first time, it is recommended to charge it for 3 hours.
- (j) The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.





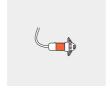
To check the remaining battery capacity of the Power Pack, press the battery check push button. The indicator lights will show the status.

(j) Please ensure to charge the Power Pack within operating temerature range: +5° to +40° Celsius (41° to 104° Fahrenheit)

5. Left & right hearing aid markings

There is a red or blue marking on the back of the hearing aid and on the speaker. This will tell you if it is a left or a right hearing aid.





Blue marking for **left hearing aid.**Red marking for **right hearing aid.**

6. Putting on the hearing aid



Place the hearing aid behind your ear.





Insert the earpiece into your ear canal.





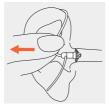
If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



7. Removing the hearing aid



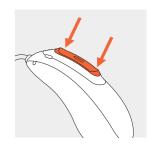
Pull on the bend of the tube and remove the hearing aid from behind the ear.



8. Multi-function button

The multi-function button has several functions.

It functions as an on/off switch, a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual "Hearing aid instructions". Please ask your hearing care professional for a printout.

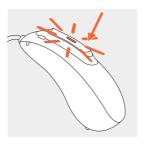


If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

9. On/Off

Switch on hearing aid

The hearing aid is configured to switch on automatically when removed from the charger. If this function is not configured, firmly press and hold the lower part of the button for 3 seconds until the indicator light blinks. Wait until the solid green light indicates the hearing aid is ready.



Switch off hearing aid

Press and hold the lower part of button for 3 seconds until the solid red light indicates the hearing is off.

0 0 0	Blinking green	Hearing aid is switching on
	Solid red for 2 seconds	Hearing aid is switching off

i When you switch on the hearing aid you might hear a start-up melody.

10. Tap control

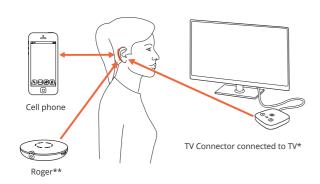
Tap control is only available for models 5 and 4. If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in your individual "Hearing aid instructions".

To use tap control tap the top of your ear twice.



11. Connectivity overview

The illustration below shows the connectivity options available for your hearing aid.



12. Initial pairing

12.1 Initial pairing to Bluetooth® enabled device

(i) It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your hearing aids will connect automatically to the device. Initial pairing can take up to 2 minutes.



On your device (e.g. a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.



Switch on both hearing aids. You now have 3 minutes to pair your hearing aids with your device.



^{*} The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

^{**}Roger wireless microphones can be connected to your hearing aids as well.



Your device shows a list of Bluetooth enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.

(i) For more information about pairing instructions for Bluetooth wireless technology, specific to some of the most popular phone manufacturers, contact your hearing care professional.

12.2 Connecting to the device

After your hearing aids have been paired to your device, they will automatically connect again when switched on.

- i The connection will be maintained as long as the device remains ON and within range.
- i Your hearing aid can be connected to up to two devices and paired to up to eight devices.

13. Phone calls

Your hearing aids connect directly with Bluetooth® enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.



Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

13.1 Making a call

Enter the phone number and press the dial button. You will hear the dialing tone through your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

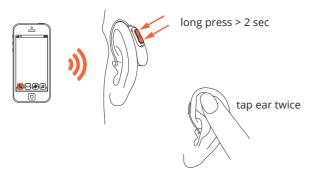
13.2 Accepting a call

When receiving a call, a calling notification will be heard in the hearing aids. The call can be accepted by taping the top of your ear twice (only available for models 5 and 4), a short press on the upper or lower part of the multi-function button on the hearing aid (less than 2 seconds) or directly on your phone.



13.3 Ending a call

A call can be ended by taping the top of your ear twice (only available for models 5 and 4), a long press on the upper or lower part of the multi-function button on the hearing aid (more than 2 seconds) or directly on your phone.



13.4 Rejecting a call

An incoming call can be rejected by a long press on the upper or lower part of the multi-function button on the hearing aid (more than 2 seconds) or directly on your phone.



14. Flight mode

Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

14.1 Enter flight mode

To enter flight mode, follow these instructions for both hearing aids separately:



1.		If the hearing aid is turned off, proceed to Step 2. If the hearing aid is on, turn it off by pressing and holding the lower part of the button for 3 seconds, until the indicator light turns solid red for 2 seconds, signifying that the hearing aid is switching off.
2.	0 0 0	Press and hold the lower part of the button. The green indicator light blinks when the hearing aid starts up.
3.		Keep pressing the button for 7 seconds, until the indicator light is solid orange, then release the button. The solid orange light indicates the hearing aid is in flight mode.

In flight mode, your hearing aid cannot connect directly to your phone.

14.2 Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid: Switch the hearing aid off and then on again - refer to chapter 9.



15. Rebooting your hearing aid

Use this technique if your hearing aid is in an error state. This will not remove or delete any program or settings.



Press the lower part of the button for at least 15 seconds. It does not matter if the hearing aid is switched on or off before you start pressing the button. There is no light or acoustic notification at the end of the 15 seconds.



Place the hearing aid in the power-connected charger and wait until the indicator light blinks green. This can take up to 30 seconds. The hearing aid is now ready to use.

16. Operating conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides.

Please ensure to use, charge, transport and store the hearing aids and the Power Pack according to the following conditions:

	Use	Charging	Transport	Storage
Temperature Maximum range	+5° to +40°C (41° to 104°F)	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F	-20° to +60°C (-4° to 140°F)
Recommended range	+5° to +40°C (41° to 104°F)	+7° to +32°C (45° to 90°F)	0° to +20°C (32° to 68°F)	0° to +20°C (32° to 68°F)
Humidity Maximum range	0% to 85% (non condensing)	0% to 85% (non condensing)	0% to 70%	0% to 70%
Recommended range	0% to 60% (non condensing)	0% to 60% (non condensing)	0% to 60%	0% to 60%
Atmospheric pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

Please ensure to charge the hearing aids and the Power Pack regularly during long-term storage.

These hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. They can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. These hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

17. Care and maintenance

Diligent and routine care of your hearing aid and chargers contribute to outstanding performance and a long service life. To ensure a long service life, the manufacturer provides a minimum of a five year service period after phase out of the respective hearing aid.

Please use the following specifications as a guideline. Further information regarding product safety, see chapter 23.2.

General information

Before using hair spray or applying cosmetics, you should remove your hearing aid from your ear, because these products may damage it.

Your hearing aids are resistant to water and dust under the following conditions:

- After exposure to water or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.
- (i) Always make sure that the hearing aids and charger are dry and clean before charging.
- (j) Always make sure that the charger is disconnected from the power mains before cleaning.

Daily

Hearing aid: Inspect the earpiece for earwax and moisture deposits. Clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. It is not recommended to rinse with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying capsules.

Chargers: Make sure that charger inserts are clean. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

Hearing aid: Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in-depth maintenance instructions or for more than basic cleaning, please see your hearing care professional. Clean the charging contacts on the hearing aid with a soft, damp cloth. **Chargers:** Remove dust or dirt from the charger inserts.

18. Exchanging the earwax protection

Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

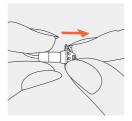
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular speaker, and every one to two weeks on the ActiveVent™ speaker.

18.1 Regular speaker with dome

18.1.1 Removing the earpiece from the speaker

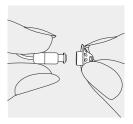


Remove the earpiece from the speaker by holding the speaker in one hand and the earpiece in the other.



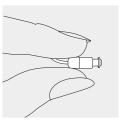


Gently pull off the earpiece to remove.





Clean the speaker with a lint-free cloth.



18.1.2 Exchanging the earwax protection with CeruShield™ Disk



Gently rotate the CeruShield Disk in the direction indicated by the arrows until a free opening appears under the bin icon.







To remove a used earwax protector carefully insert the speaker into the free opening (under bin icon) until it clicks. After the click you will see the removed earwax protector in the opening below the bin icon.



To insert a new earwax protector carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. After the click you will see the opening below is empty and the new earwax protector sits in the speaker.



18.1.3 Attaching the earpiece to the speaker



Hold the speaker in one hand and the earpiece in the other.



2

Slide the earpiece over the speaker sound outlet.





The speaker and the earpiece should fit perfectly together.



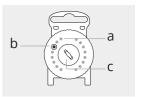
18.2 ActiveVent™ speaker with SlimTip™

18.2.1 Parts Explanation



wax filter dispenser

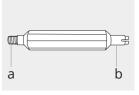
- a) rotating disk
- b) new filter
- c) dispensing slot for used filters





changing tool

- a) screw end for removing used filter
- b) forked end for inserting new filter



18.2.2 External cleaning

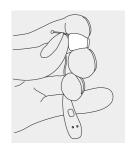


Wipe the earpiece and the speaker port to remove earwax.

18.2.3 Removing the used wax filter (HF3 Filter)

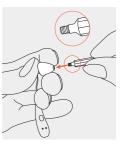


Hold the earpiece firmly and secure the rear of the speaker with your finger.



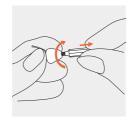


Insert the screw end of the HF-3 changing tool into the speaker of the hearing aid.





Rotate the changing tool clockwise until some resistance is felt.
Pull the changing tool out of the speaker with the used wax filter attached to the end.





Slide the changing tool to either side of the slot. Lift the changing tool up, leaving the used wax filter in slot.





Insert the used wax filter into the dispensing slot in the middle of the wax filter dispenser.



18.2.4 Inserting a new wax filter



After removing the used wax filter from the speaker of the hearing aid, brush away any remaining debris. Rotate the ridged disk of the wax filter dispenser until a new wax filter is visible in the window of the disk.



19. Service and warranty

Local warranty

Please ask the hearing care professional where you purchased your hearing aids and chargers about the terms of the local warranty.

International warranty

The manufacturer offers a one year limited international warranty, valid from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid and chargers respectively, but not accessories such as tubes, earpieces, external speakers. The warranty only comes into force if a proof of purchase is shown.

The international warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods.

Warranty limitation

Authorized hearing care professional (stamp/signature):

This warranty does not cover damage from improper handling or care, exposure to chemicals or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void. This warranty does not include any services performed by a hearing care professional in their office.

Serial numbers Hearing aid left side: Hearing aid right side:	
ampli-charge B-R 1: ampli-charge R small 1: ampli-charge R 1 compact: Power Pack:	
Date of purchase:	

20. Compliance information

Europe:

Declaration of Conformity for the hearing aid

Hereby the manufacturer declares that this product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio Equipment Directive 2014/53/EU. The full text of the EU Declaration of Conformity can be obtained from the manufacturer: www.sonova.com/en/certificates

Australia/New Zealand:



D NI

Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.

The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

Radio information of your wireless hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz - 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 2.5mW
Bluetooth®	
Range	~1m
Bluetooth	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Compliance with emission and immunity standards

Emission standards	EEN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11
	CISPR32
	CISPR25
	EN 55025

Immunity standards	EN 60601-1-2	
	IEC 60601-1-2	
	EN 61000-4-2	
	IEC 61000-4-2	
	EN IEC 61000-4-3	
	IEC 61000-4-3	
	EN 61000-4-4	
	IEC 61000-4-4	
	EN 61000-4-5	
	IEC 61000-4-5	
	EN 61000-4-6	
	IEC 61000-4-6	
	EN 61000-4-8	
	IEC 61000-4-8	
	EN 61000-4-11	
	IEC 61000-4-11	
	IEC 60601-1	
	ISO 7637-2	

21. Information and description of symbols



With the CE symbol, the manufacturer confirms that this product – including accessories – meets the requirements of the Medical Devices Directive 93/42/ EEC as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the hearing aid is specified as an applied part of Type B.



Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC.



Indicates the date when the medical device was manufactured

EC RE

Indicates the Authorized representative in the European Community. The EC REP is also importer to the European Union.



This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.



Important information for handling and product safety.

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This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.



Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia



Indicates the manufacturer's serial number so that a specific medical device can be identified.



Indicates the manufacturer's catalogue number so that the medical device can be identified.



Indicates that the device is a medical device.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices related to batteries in these user guides



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides

IP Rating = Ingress Protection Rating, IP68 rating indicates that the hearing aid is water and dust resistant. It survived continuous immersion in 1 meter of water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard



Temperature during transportation and storage: -20° to +60° Celsius (-4° to +140° Fahrenheit).



Humidity during storage: 0% to 70%, if not in use. See instruction in chapter 23.2 regarding drying the hearing aid after use.



Atmospheric pressure during transportation and storage: 500 hPA to 1060 hPa



During transportation keep dry.



The symbol with the crossed-out garbage bin is to make you aware that this hearing aid as well as chargers may not be thrown away as normal household waste. Please dispose of old or unused hearing aids and charger, at waste disposal sites intended for electronic waste, or give your hearing aid and charger to your hearing care professional for disposal. Proper disposal protects the environment and health.

Symbols applicable to the European power supply only

Power supply with double isolation.
Device designed for indoor use only.

Safety isolating transformer, short circuit proof.

22. Troubleshooting

/earpiece blocked aid switched off fully discharged aid not inserted correctly into ear n in ear canal too loud
fully discharged aid not inserted correctly into ear n in ear canal too loud
aid not inserted correctly into ear n in ear canal too loud
n in ear canal too loud
too loud
r 1 -
too low
tery
/earpiece blocked
has changed
on for low battery
fully discharged
vas inadvertently deactivated by the button longer than 15 seconds
aid not inserted correctly rger
not connected to power source
fully discharged
f

What to do

What to do
Clean speaker opening/earpiece, or change wax filter
Press lower part of multi-function button for 3 seconds
Charge hearing aid (chapter 4)
Insert hearing aid correctly (chapter 6)
Contact your ENT/GP or hearing care professional
Decrease volume if volume control available (chapter 8)
Increase volume if volume control available (chapter 8)
Charge hearing aid (chapter 4)
Clean speaker opening/earpiece, or change wax filter
Contact you hearing care professional
Charge hearing aid (chapter 4)
Charge hearing aid (chapter 4)
Perform step 2 of the rebooting process (chapter 15)
Insert hearing aid correctly into charger (chapter 4)
Connect charger to external power supply (chapter 3)
Wait three hours after placing hearing aid in charger, regardless of LED behavior

Problem	Causes
Indicator light on hearing	Dirty charging contacts
aid is solid red while hearing aid is in the charger	Hearing aid is out of its operating temperature range
	Faulty battery
Indicator light on hearing aid switches off when hearing aid is removed from charger	"Auto On" feature is disabled
Indicator light on hearing aid remains solid green after removal from charger	Indicator light on hearing aid was red when hearing aid was placed into the charger
Hearing aid with	Vent in wrong position (e.g. closed)
ActiveVent [™] receiver is not working properly	Wax
Working property	Other
ActiveVent speaker feels loose in earpiece or has separated completely from earpiece	Speaker dislodged from earpiece (i.e during exchange of earwax protection)

What to do

Clean the contacts of the hearing aid and the charger Warm hearing aid up. Operating temperature range is +5° to +40° Celsius (+41° to +104° Fahrenheit) Contact your hearing care professional Switch on the hearing aid (chapter 9)

Reboot the hearing aid (chapter 15)

Switch hearing aid off and then on again (chapter 9)

Clean the speaker opening and / or change the wax filter (chapter 18.2) Contact your hearing care professional

Push the speaker back into the earpiece. If the speaker is still loose contact your hearing care professional.

Problem	Causes	
Battery does not last the whole day	Shortened battery life	
Phone call function does	Hearing aid is in flight mode	
not work	Hearing aid not paired to the phone	
Charging does not start	Charger not connected to power supply	
(no power pack used)	Hearing aid not inserted correctly into charger	
Charging does not start when using Power Pack	Power Pack discharged	

What to do

Contact your hearing care professional. A battery replacement may be required
Switch hearing aid off and then on again (chapter 14.2)
Pair hearing aid to the phone (chapter 12)
Connect charger to power supply or Power Pack (chapter 4.2)
Insert hearing aid correctly into charger (chapter 4.1)
Charge Power Pack (chapter 4.2)

(i) If the problem persists, contact you hearing care professional for assistance.

23. Important safety information

Please read the information on the following pages before using your hearing aid.

Intended use:

The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

The Tinnitus Balance software feature is intended for use by people with tinnitus who also desire amplification. It provides supplementary noise stimulation which can help focus the user`s attention away from their tinnitus.

Indications:

Presence of hearing loss.

Presence of hearing loss in combination with tinnitus.

Contraindications:

Evidence of active or chronic middle or outer ear pathology, chronic drainage or discharge, evidence of chronic inflammation.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Infrequent use of a hearing aid does not permit a user to attain full benefit from it. The use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

The hearing aid is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc.

Target population:

The target population is primarily the adult population over 18 years of age. This product may also be used with

children 36 months of age or older (not applicable in combination with ActiveVent™ speaker). Individuals with cognitive impairment will require constant supervision by a caregiver. The target group for the Tinnitus Balance software feature are adults 18 years of age or older with tinnitus who also desire amplification.

Any serious incident that has occurred in relation to the hearing aid, should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:

- a) the death of a patient, user or other person
- b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- c) a serious public health threat

To report an unexpected operation or event, please contact the manufacturer or a representative.

23.1 Hazard warnings

The rechargeable hearing aids contain lithium-ion batteries and the Power Pack contains a lithiumpolymer battery that can be taken onto airplanes as carry-on luggage. The Power Pack cannot be placed in the checked-in baggage and can only be placed in the carry-on luggage.

1 Your hearing aids operate between 2 4 GHz -2 48 GHz frequency range. When flying please check if flight operator requires devices to be switched

into flight mode, see chapter 14.

⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.

Changes or modifications to the hearing aid that were not explicitly approved by the manufacturer are not permitted. Such changes may damage your ear or the hearing aid.

⚠ Do not use the hearing aids and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled) or where electronic equipment is prohibited.

⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.

Titanium shells of custom hearing aids and earpieces can contain small quantities of acrylates from adhesives. People who are sensitive to such substances may potentially experience an allergic skin reaction. Please stop using the device immediately if such a reaction occurs and check with your hearing care professional or physician.

⚠ In very rare cases, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get

stuck in your ear canal, it is strongly recommended to see a physician for safe removal. To prevent pushing the dome towards the eardrum, never try to re-insert the speaker into the ear canal.

Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

Keep the ampli-charge R 1 compact out of reach of children, individuals with cognitive impairment and pets. If the drying capsule is swallowed, consult a physician or hospital immediately.

Only authorized personnel are allowed to open the Power Pack due to possible electrical hazard.

Do not cover the whole charger cases while charging, e.g. with a cloth etc.

⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):

- Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (i.e. EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.

 If using a wireless accessory produced by the manufacturer or by Phonak AG, consult the chapter "Important safety information" in your wireless accessory user guide.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ The USB port of the charger is to be used for the described purpose only.

For charger, use only IEC 62368-1 and IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

⚠ Hearing aids should not he fitted with domes / wax protection systems when used by clients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal

Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.

After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.

Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids, the Lyric SoundLync, the Lyric programming wand and the MiniControl contain static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.

The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

WARNING: This device uses a lithium button/coin battery. These batteries are hazardous and can cause severe or fatal injuries in 2 hours or less if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

23.2 Information on product safety

- These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.
- Never wash the microphone inputs.
 Doing so could cause it to lose its special acoustic features.
- Protect your hearing aid and charging accessories from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid or charging accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.

- i Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- i The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.

- Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or charging accessories.
- (j) Charger, Power Packs, and power supply must be protected against shocks. If the charger, Power Pack or power supply is damaged after a shock, the devices must not be used anymore.
- If you are not using your hearing aid for a long period of time, store it in a box with a drying capsule or in a well ventilated location.

This allows moisture to evaporate from your hearing aid and prevents a potential impact on its performance.

- (i) Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them outside the examination room/area before undergoing:
 - Medical or dental examination with X-ray (also CT scan).
 - Medical examinations with MRI/NMRI scans,

generating magnetic fields. Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.

- Do not use your hearing aid in areas where electronic equipment is prohibited.
- The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.

- (i) Only use approved chargers and Power Packs described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- (j) Your hearing aid(s) contain lithium-ion batteries and the Power Pack contains a lithium-polymer battery, both with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of lithium-ion batteries.
- (j) Your hearing aid(s) may contain personal data. Please ensure safe disposal to prevent any misuse.

Notice 1:

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.

Notice 2:

Changes or modifications made to this device not expressly approved by Sonova AG may void the FCC authorization to operate this device.

Notice 3:

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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DOC Regulatory Applicability Device Master Record (DMR) **DOC Regulatory Applicability** Design History File (DHF)

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PDL-5606 [3]	029-0851-07 User guide Ampli-energy R P R PH - NL	DOCUMENT	Related
PDL-9500 [2]	029-0851-12 User guide Ampli-energy R P R PH - PT	DOCUMENT	Related
PDL-5648 [3]	029-0851-06 User guide Ampli-energy R P R PH - ES	DOCUMENT	Related

Approvals

Leve	el Actor	Job Title	Sign-off Date	Sign-off By
1	Lora Braun	Quality Assurance Manager	16-Aug-2022	11LBRAUN
2	Jérôme Assal	Marketing Senior Product Manager Lyric	16-Aug-2022	11JASSAL

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Access Activity	<u>Note</u>	Accessed By	Accessed Date
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